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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,783	05/27/2004	Mohammed Moin Hussaini	146128CT	3782

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EXAMINER	
HORWAT, JENNIFER A	

ART UNIT	PAPER NUMBER
3768	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/709,783	HUSSAINI ET AL.	
	Examiner	Art Unit	
	Jennifer Horwat	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/27/2006 have been fully considered but they are not persuasive.

Regarding claim 1, in response to the argument that the entry path is substantially different than the distal tip of the probe, the two will be identical at the very least at the time of initial positioning when the initial path is determined at the entry position. The trajectory path is in fact determined based on the initial skin entry position and the target position, as shown in figure 1, points A' and T, where point A' is located on the skin.

Regarding claim 3, applicants argue that a threshold value and that movement does not occur at a predetermined respiratory state. However, examiner notes that in this instance the predetermined respiratory state is the minimum inspiration point (col 9, line 61) and that a tolerance or maximum deviation, or threshold, from this point is used to determine when the patient is in the predetermined respiratory state. The probe is advanced when the patient is in the preselected respiratory state (col 3, lines 50-52). Regarding claims 6 and 15, movement of the end effector during a predetermined respiratory state is disclosed by Acker and discussed above. Further, applicants argue that insertion of the needle as disclosed by Stoinovici would render the system disclosed by Acker unsatisfactory for its intended purpose. However, the system of Acker also is used for positioning of a biopsy needle (col 10, line 48). Stoianovici was

used as a reference to show that computer controlled advancing of a probe or needle is well known in the art. In light of the teachings by Stoianovici, it is an obvious modification to use automatic advancement as opposed to hand held advancement as disclosed by Acker. Examiner maintains that this improvement to Acker does not render the system of Acker moot as stated by applicant.

2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to do so is found in the general knowledge available to one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Acker (US 6580938). Acker discloses a method and system for image guidance of a probe wherein a plurality of images are acquired, in one embodiment by CT, at a

selected respiratory state (col 7, lines 60-66) on which entry and target positions may be displayed along with a trajectory computed between the two (figure 1, elements A', T, and 66). The probe is advanced when the patient is in the selected respiratory state (col 3, line 50), which is determined when motion due to respiration is within a predetermined tolerance of the desired respiratory state (col 10, lines 3-4). It is inherent in the use of a CT system that the patient is moved into the system and cross-sectional images are obtained during the movement.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 4, 6, 8-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker in view of Stoianovici, et al (US 2004/0162486). Acker, as discussed above, discloses a manual system for image guidance of a probe and fails to disclose using the method with under computer assistance. The system disclosed by Acker determines when the probe or needle should be advanced based on when the patient is substantially within the predetermined repiratory state. This determination is done by a computer, and the result of this computation is interpreted to be a "gating signal". Stoianovici discloses a system related to robotic devices used in computer-assisted surgery. The system is coupled with a percutaneous access of the kidney (PAKY) needle driver wherein the computer assisted surgery robot aligns the needle (paragraph 30) and the needle is then driven along the trajectory calculated between the target and

skin entry points (paragraphs 41 and 65) selected by the user. As the movement of the needle is determined by the hardware controlling the PAKY needle driver system, the speed and movement of the needle is inherently predetermined by the computer and sent to the robot moving the needle (figure 1). It is inherent that the computer assisted surgery system and the image guidance system have the required code on computer readable medium that control the operations of the systems previously discussed. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Acker with the disclosure of Stoianovici as the alignment and insertion of the needle will be more accurate than if done freehand as in the system disclosed by Acker.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Acker and Stoianovici as applied to claim 6 above, and further in view of Schweikard, et al (US 6144875). The system disclosed by Acker uses external field transducers to monitor the respiration state of the patient and does not explicitly disclose the use of infrared to monitor respiration. Schweikard discloses an apparatus and a method for compensating for respiratory and patient motion during treatment using infrared to track external markers (col 6, line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosures of Acker and Schweikard with the teachings of the reference by Schweikard, as it is well known in the medical imaging art to substitute one type of detector for another to serve the same purpose.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jah
6/7/06

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